

U.S. Application Serial No. 10/603,279  
RCE filed on April 7, 2006

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### REMARKS

The Applicants thank the Examiner for the consideration shown the present application thus far. Claims 1-5, 8-15, 21-25 and 41-44 are pending and stand finally rejected. Claims 6, 7, 16-20 and 26-40 are canceled by the present Amendment.

#### 35 U.S.C. § 112 Rejection

Claims 11-30 and 41-44 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Examiner states that the term "reduced" in Claims 11-30 and 41-44 is a relative term and therefore renders the claims indefinite.

By the present Amendment, claims 1, 10, 11, 21, 41 and 43 have all been amended to clarify the meaning of the term "reduced". Moreover, all of the rejected claims have either been amended to define the term reduced or depend from one of the amended claims.

As such, Applicants respectfully request reconsideration and allowance of Claims 11-30 and 41-44 over the Examiner's 35 U.S.C. § 112, second paragraph, rejection.

#### 35 U.S.C. § 103 Rejection

Claims 1-5, and 7-44 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Elder, et al. (U.S. Patent Application No. 2004/0058054—hereinafter, Elder '054). The Applicants respectfully traverse this rejection.

The Examiner states that Elder '054 discloses "a method for reducing the amount of acrylamide in thermally processed foods". The Examiner points out that Elder '054 discloses contacting asparagine with the enzyme asparaginase. The Examiner further notes that Elder '054 provides in Example 5 proof that acrylamide reduction was reduced by more than 99.9%. The Examiner then sums up by stating that it would have been obvious to one of ordinary skill in the art to have added an asparaginase enzyme to corn-based food material prior to heating/cooking in order to reduce the level of asparagine within the corn-based food material.

The Examiner bears the burden of factually supporting any prima facie conclusion of obviousness. In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. See Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fe. Cir. 1983). Distilling the invention down to the "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." See W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983). Inventors of unobvious compositions, such as those of the present invention, enjoy a *presumption* of non-obviousness,

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which must then be overcome by the Examiner establishing a case of prima facie obviousness by the appropriate standard. If the Examiner does not prove a prima facie case of unpatentability, then without more, the Applicant is entitled to grant of the patent. See *In re Oetiker*, 977 F.2d 1443.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all of the claim limitations.<sup>1</sup>

With regard to this obviousness rejection, Applicants respectfully disagree with the Examiner and assert that Elder '054 not only does not teach or suggest Applicants' invention but also fails to provide a reasonable expectation of success between its examples, particularly example no. 5, and the claimed subject matter of Elder '054, namely reducing the presence of acrylamide in thermally processed food. In so doing, Elder '054 has failed to appreciate the difficulty in adding or applying an asparagine-reducing enzyme to corn-based food material.

To begin, Applicants note that there are stark differences between 1) Applicants' corn-based food material and Elder's simple sugar and amino acid filled test tube and 2) reducing the levels of asparagine and/or acrylamide in corn-based food material versus that of simple sugar and amino acid. Looking carefully at the Example Nos. 1-5 of Elder '054, one immediately understands that the reduction of either asparagine or acrylamide is never achieved in food, or any edible, complex multi-celled structure like corn-based food material. Rather, Elder '054 merely adds simple sugar to amino acid in test vials, heats the materials, adds asparaginase and then records, essentially, the reaction of asparaginase to the sugar/amino acid combination in the way of reduced levels of acrylamide formed. More specifically, Elder '054 only shows the reduction of acrylamide in one example, namely, Example No. 5.

In Example No. 5, glucose is added to asparagine and then heated to form acrylamide. Next, asparaginase is added to the glucose/asparagine mix. Subsequently, the acrylamide levels are measured and compared with two untreated controls. Although a reduction in acrylamide is shown, Applicants assert that such experiments, without more, do not provide a reasonable expectation of success that one of skill in the art reading Elder '054 would be able to reduce asparagine/acrylamide in food, or any edible, complex multi-celled structure like corn-based food material. Elder's Example No. 5 is limited only to test vials with ingredients that cannot fairly be said to be corn-based food material or any other kind of food. Rather, the components glucose

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<sup>1</sup> *In re Vaeck*, 947 F. 2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

and asparagine represent the most basic building blocks of many foods but lack the complex structure of most foods, e.g., Applicants' corn-based food material.

Furthermore, Elder '054 only mentions that asparaginase can be used to come into "contact" with the simple sugar/amino acid combination. Other than putting asparaginase in the test tubes of Example No. 5, the nature of this "contact" is never explained, defined or taught. Applicants' "contact" of their asparagine-reducing enzyme is much more robust and definitive.<sup>2</sup> Applicants' disclosure is extensive and details their break-through ability of adding an asparagine-reducing enzyme to corn-based food material to reduce asparagine levels in the beans. Such detailed addition is necessary because of complex multi-celled structures like corn-based food material. One of skill in the art knows that in order to penetrate the cell walls of, say, corn-based food material, much work and energy must be applied in order to reach the interior of the cells of the corn-based food material; i.e., the cite where asparagine is produced. Such difficulty is not appreciated by Elder '054.

As such Elder '054 has not taught or suggested Applicants' invention and furthermore has merely made unsubstantiated assertions of acrylamide reduction in food based on examples that do not teach or suggest the reduction of asparagine/acrylamide in corn-based food material or any other kind of food.

Applicants therefore respectfully request reconsideration and allowance of Claims 1-5 and 7-44 over the Examiner's 35 U.S.C. § 103(a) rejection in view of Elder '054.

With regard to Claims 41-44 the Examiner states that it would have been obvious to one of ordinary skill in the art to have packaged and appropriately labeled the food products produced by Elder '054. Such packaging techniques, notes the Examiner, were well known in the art. The Examiner further states that if Applicants' product claims are found to be allowable, then the article container claims 17-18 would also be allowable.

Applicants respectfully disagree with the Examiner's assertions. Applicants' respectfully assert that the Examiner is using the wrong test for obviousness. The test is whether the reference itself, herein Elder '054, or knowledge generally available to one of skill in the art teaches or suggests Applicants' invention. Applicants assert that neither condition has been met.

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<sup>2</sup> Applicants' Specification at page 5, lines 32-35 to page 6, lines 1-2: "The enzyme may be added to the corn-based food material in any suitable form. For instance, the enzyme may be added as a powder or in the form of a solution. Furthermore, the enzyme may be added to the corn-based food material in any suitable manner, such as directly (for example, sprinkled, poured, or sprayed on the corn-based food material, or the corn-based food material can be soaked in an enzyme solution) or indirectly. [Applicants' disclosure is replete with this kind of detailed teaching.]

First, nothing in Elder '054 teaches or suggests an article of commerce that communicates the reduction or lowness of acrylamide in Applicants' corn-based food material or any other kind of food. As noted extensively herein, Elder '054 does not itself teach the reduction of acrylamide in corn-based food material or of any other food, but merely a reaction of an enzyme with asparagine and simple sugar in a test vial.

Second, Applicants assert that one of skill in the art would not have been led to produce an article of commerce that communicates the reduction of acrylamide in corn-based food material or any other kind of food. Heretofore, the ability to reduce acrylamide in edible structures producing asparagine has never been accomplished until Applicants accomplished this reduction. Thus, there was no knowledge generally held available to one of skill in the art that such a claim, i.e., the reduction or lowness of acrylamide in food, was possible or even desired. Applicants point out that they claim an article of commerce having a message informing a consumer that the product has a reduced level of acrylamide. Applicants are not claiming a generic message or merely words on a package which is within the knowledge of one of ordinary skill in the art. Rather, Applicants' message is specific to a heretofore unobtainable function by any one of skill in the art save Applicants. Such a message is therefore not within the knowledge of one of ordinary skill in the art.

Thus, Applicants respectfully request reconsideration and allowance of Claims 41 and 44 over the Examiner's 35 U.S.C. § 103(a) rejection in view of Elder '054.

#### **Double Patenting - Non-Statutory**

Claims 41-44 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-12 of co-pending Application No. 10/606,260. If the claims are still rejected under the judicially created doctrine of obviousness-type double patenting after the rejections addressed above are resolved, then the Applicants will file an appropriate Terminal Disclaimer.

Claims 1-5, and 7-44 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-32, and 42-50 of co-pending Application No. 10/606,137. If the claims are still rejected under the judicially created doctrine of obviousness-type double patenting after the rejections addressed above are resolved, then the Applicants will file an appropriate Terminal Disclaimer.

Claims 11-44 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-14 of co-pending Application No. 10/603,978. If the claims are still rejected under the judicially created doctrine of

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obviousness-type double patenting after the rejections addressed above are resolved, then the Applicants will file an appropriate Terminal Disclaimer.

Respectfully submitted,

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